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08/991143

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/991143	10/14/98	COMTECH INC	800.423081

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EXAMINER

ART UNIT PAPER NUMBER

1544

DATE MAILED: 09/14/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 6/10/1998

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 0 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-33 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-33 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

☒ Restriction/Election FAX - SEE OFFICE ACTION ON THE FOLLOWING PAGES-

DETAILED ACTION

1. Effective February 7, 1998, the location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Technology Center 1600.

Election/Restriction

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I Claims 1-16 and 31, drawn to a method of preventing an indication/disease by administering an epitope peptide, classified in Class 424, subclasses 185.1 and 810, and Class 514, subclass 885.

Group II. Claims 17, 18, and 31, drawn to a method of tolerization to an antigen, classified in Class 424, subclasses 184.1 and 810.

Group III. Claims 19 and 20, drawn to a method of identifying an immunodominant epitope, classified in Class 435, subclass 4.

Group IV. Claim 21, drawn to a method of identifying a universal epitope, classified in Class 435, subclass 4.

Group V. Claims 22 and 31, drawn to a method of treating a gene therapy patient with anti-viral vector epitope, classified in Class 424, subclass 204.1.

Group VI. Claims 23 and 31, drawn to a method of inhibiting a response to an exogenously added protein, classified in Class 424, subclass 278.1.

Group VII. Claims 24 and 31, drawn to a method of inhibiting a response to a gene encoding exogenously added protein, classified in Class 424, subclass 93.1 and Class 514, subclass 44.

Group VIII. Claims 29 and 30, drawn to a tolerogen, classified in Class 424, subclass 204.1.

Group IX. Claim 32, drawn to a method of inhibiting antibody-mediated disease, classified in Class 424, subclass 184.1.

Group X. Claim 33, drawn to a method of inhibiting antibody-mediated disease, classified in Class 424, subclasses 184.1 and 278.1.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions VIII and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process. The tolerogen can be used to generate antibodies.

4. Inventions I, II, III, IV, V, VI, VII, IX, and X are different methods of use. These inventions require different ingredients, process steps and endpoints to accomplish the use of method of preventing an indication/disease by administering an epitope peptide, method of tolerization to an antigen, method of identifying an immunodominant epitope, a method of identifying a universal epitope, a method of treating a gene therapy patient with anti-viral vector epitope, a method of inhibiting a response to an exogenously added protein, a method of inhibiting a response to a gene encoding exogenously added protein, and a method of inhibiting antibody-mediated disease. Therefore, they are patentably distinct.

5. Inventions VIII and I/III/IV/V/VI/VII/IX/X are not related as products and a method of use. Therefore, they are patentably distinct.

6. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-X is not required for any other group from Groups I-X and Groups I-X have acquired a separate status in the art as shown by their different classification in addition to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is further required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

If Group I is elected, Applicant is required to elect a *specific* embodiment of an antigen.

If Group V is elected, Applicant is required to elect a *specific* viral epitope.

If Group VI is elected, Applicant is required to elect a *specific* disease or indication.

If Group VII is elected, Applicant is required to elect a *specific* disease or indication.

These species are distinct because their structures or modes of action are different. The pathological conditions differ in etiology and therapeutic endpoints.

8. Applicant is required to elect a single disclosed species even though this requirement is traversed.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. A telephone call was made to Warren Woessner/Jan Embretson on August 18, 1998 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Rabin, Ph.D. whose telephone number is (703)

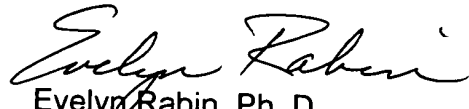
Serial Number: 08/991143
Art Unit: 1644

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305-6811. The examiner can normally be reached on Monday through Thursday from 7:30 AM to 6:00 PM.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The FAX number for this Technology Center is (703) 305-3014 or (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Evelyn Rabin, Ph.D.
September 14, 1998


Evelyn Rabin, Ph. D.
Patent Examiner
Group 1640